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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|-------------------------------|------------------|
| 10/624,713 | 07/21/2003 | Pascal Druzgala | ARYX-117XC1 | 7573 |
| 23557 7590 06/09/2004 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION 2421 N.W. 41ST STREET SUITE A-1 GAINESVILLE, FL 326066669 | | | EXAMINER AULAKH, CHARANJIT | |
| | | | ART UNIT 1625 | PAPER NUMBER |
| DATE MAILED: 06/09/2004 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--|---|--|
| Office Action Summary | Application No. 10/624,713 | Applicant(s) DRUZGALA, PASCAL | |
| | Examiner Charanjit S. Aulakh | Art Unit 1625 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>2</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-11 are pending in the application.

Oath/Declaration

2. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: It lists the application serial no. 10/624,659. The correct serial no. should be 10/624,713.

Specification

3. In brief description of drawings on page 2, the values of variables R, R1 and X present in the figures are not defined. Also, the brief description of figure 2 lists figures 2A-2S whereas figure 2 has structures 2T and 2U also. An appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for 1,3-dipropylxanthine with an ester function at the 8-position as an A1AdoR antagonist, does not reasonably provide enablement for all other A1AdoR antagonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The following eight different factors (see Ex

parte Foreman, 230 USPQ at 547; Wands, In re, 858.F. 2d 731, 8 USPQ 2d 1400, Fed. Cir. 1988) must be considered in order for the specification to be enabling for what is being claimed:

Quantity of experimentation necessary, the amount of direction or guidance provided, presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability and the breadth of claims. In the instant case, the specification is not enabling based on at least four of the above mentioned eight factors such as quantity of experimentation necessary, the amount of direction or guidance provided, presence of working examples and the breadth of claims.

The instant specification discloses only 1,3-dipropylxanthines that have an ester function at the 8-position as an antagonist of A1AdoR receptors. There is no teaching in the specification of any other A1AdoR antagonists. There are no working examples present showing metabolism, half-life, their metabolites etc. of any other antagonist. There is no guidance or direction provided how to select an A1AdoR antagonist having one of the characteristics described in steps a through h. The instant A1AdoR antagonist encompasses hundreds of thousands of compounds and therefore, in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to select A1AdoR antagonists that have at least one characteristic described in steps a through h.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In independent claims 1, 4 and 7, the term ---An A1AdoR antagonist--- is indefinite since specific antagonists and their metabolites are not defined and furthermore, steps for assessing or investigating one of the characteristics a through h are not defined. How to measure inhibitory activity at IKR (HERG) channel? What is meant by DDI and LFT values? The applicants are suggested to include specific structure of the antagonist in the claim.

In claims 3, 6 and 9, the value of variable X is not defined.

In claim 7, what is the benefit of inhibiting A1AdoR receptor in an individual and furthermore, why an individual needs treatment? What is being treated here?

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Rzeszotarski (U.S. Patent no. 4,783,530).

Rzeszotarski discloses 8-aryl xanthines having adenosine A1 receptor antagonist activity. The compound disclosed in table (see columns 13-14) where R1 and R2 represent Pr, R3 represents H and R4 represents COOEt clearly anticipates the instant claims.

9. Claims 1, 2, 4, 5, 7, 8, 10 and 11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Kufner-Muhl (U.S. Patent no. 5,696,124, cited on applicants form 1449).

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Kufner-Muhl discloses Xanthine derivatives with adenosine-antagonist activity. The compounds 6, 7 and 8 directed to 1,3-dipropylxanthines having an ester function at the 8-position (see columns 20-21) disclosed by Kufner-Muhl clearly anticipate the instant claims.

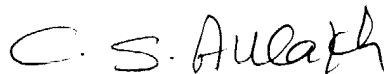
10. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Katsushima (J. med. Chem., cited on applicants form 1449).

Katsushima discloses 8-cycloalkyl-1,3-dipropylxanthines as antagonists of adenosine receptors. The compound no. 5 (see tables I and II on page 1907) disclosed by Katsushima clearly anticipates the instant claims.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charanjit S. Aulakh whose telephone number is (571)272-0678. The examiner can normally be reached on Monday through Friday, 8:30 A.M. to 5:00 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571)272-0699. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Charanjit S. Aulakh
Primary Examiner
Art Unit 1625